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PATENT & TRADEMARK OFFICE

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

HIRAYAMA, Kouji, et al.

Docket No: Q65805

Appln. No.: 09/933,000

Group Art Unit: 1743

Confirmation No.: 6965

Examiner: Lyle Alexander

Filed: August 21, 2001

For: TEST APPARATUS FOR ASSAYING A COMPONENT IN A LIQUID SAMPLE

REPLY BRIEF PURSUANT TO 37 C.F.R. § 1.193(b)

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 1.193(b), Appellant respectfully submits this Reply Brief in response to the Examiner's Answer dated May 28, 2004. Entry of this Reply Brief is respectfully requested.

POINTS RAISED IN EXAMINER'S ANSWER

The Examiner's Answer continues to maintain the rejection of the claims on appeal, and for the reasons set forth in Appellant's Appeal Brief, the rejection should be reversed.

In addition, Appellant submits the following remarks addressing certain points raised by the Examiner in his Answer regarding Appellant's "Arguments" (pages 3-9 set forth in Appellant's Appeal Brief).

First, the Examiner appears to be misconstruing the recitations of claim 11, as the Examiner asserts that the read area of EP '222 has been read on the claimed black portion of the cover. However, the detecting area of the present invention is not the claimed black portion of the cover. Claim 11 recites that "at least a portion of said cover covering the detecting area is black." Therefore, the portion of the cover and the detecting area are not the same. In addition, the detecting area is located on the lower side of both the reagent layer and the cover because the detecting area is where the reflected light is measured whereas the read area (15) of EP '222 is above the reagent matrix (14). *See* Figure 4.

Second, the Examiner asserts that Appellant states that EP '222 teach the black cover in contact with layer (3) at page 5 of the Examiner's Answer. However, Appellant did not state that EP '222 teaches a black cover in contact with layer (3). Rather, Appellants' have consistently maintained the position that EP '222 does not teach a black cover, and that the cover (17) of EP '222 is positioned above the absorbent material (16), thus the cover (17) is neither positioned above the reading area (15) nor in contact with the reagent matrix (14). *See e.g.,* page 6, lines 12-17 of Appellant's Appeal Brief.

At page 8 of Appellant's Appeal Brief, Appellant stated that, even assuming, *arguendo*, that there was some motivation to combine JP '065 and EP '222, the structure resulting from the combination would still not be the same as the structure of the present invention because the resulting structure would not have a black cover. The Figure at page 8 was intended to show a structure that would result if there were some motivation to combine JP '065 and EP '222 based on Appellant's understanding of the Examiner's rejection. However, Appellants did

not and do not concede that any motivation exists to modify the structure of JP '065 as shown in the Figure.

Third, the Examiner asserts that the teachings of EP '222 are sufficient to support modification of the cover (5) of JP '065 to contain black pigment.

Appellants emphasize again that there must be some teaching, suggestion or incentive in the prior art to support the combination, and that the mere fact that references can be combined or modified does not render the resultant combination obvious.

EP '222 discloses that background due to unbound label or chemical interferents present in the serum sample is removed by an exhaustive wash step, and that a light absorbing or reflecting means absorbs or blocks background signal generated by the wash, removed label or other interferents (chemical interferents) from outside the read area, thereby preventing the background from moving back into the read area. *See* page 2, lines 30-33; page 2, line 57 to page 3, line 2; page 7, lines 2-6 and Appellant's Appeal Brief at page 6, line 18 to page 7, line 6. In addition, EP '222 discloses that after the wash, the detection signal is measured to determine the analyte concentration. *See* page 3, lines 3-4. Therefore, in order to avoid influences of fluorescence and luminescence by soluble (chemical) interferents and unbound label in the measurement of a sample, EP '222 discloses that black materials can be used in the absorbent material or in the light absorbing or reflecting means (19).

The Examiner appears to consider interferents to include stray light. *See* Examiner's Answer at page 5. However, when EP '222 is read as a whole, EP '222 is referring to chemical interferents present in the serum sample, not to stray light. *See e.g.,* page 2, lines 30-32.

Therefore, EP '222 does not disclose or suggest the desirability to absorb or reflect stray light passed through the reagent layer or the use of a light absorbing or reflecting means to absorb or block signals generated by stray light.

JP '065 does not disclose the use of a wash, and the cover (5) of JP '065 is not in contact with the reagent layer (3). As noted above, in EP '222, in order to absorb or block signals generated by the wash or unbound label, it is necessary for the light absorbing means (19) to be in contact with reagent layer (14). Since the cover of JP '065 is not in contact with the reagent layer (3), there is no motivation that would lead one of ordinary skill in the art to modify the cover to be black. In addition, because JP '065 does not disclose the use of wash, there would be no background signal generated from the wash, unbound label or other chemical interferents. Furthermore, since EP '222 does not disclose or suggest the desirability to absorb or reflect stray light passed through the reagent layer, EP '222 does not disclose any benefit or advantage of using a black color in a cover, and thus, provides no motivation to modify the cover (5) of JP '065.

Therefore, EP '222 does not provide any motivation that would lead one of ordinary skill in the art to modify the cover (5) of JP '065.

In view if the foregoing, EP '222 does not provide any technical motivation that would lead one of ordinary skill in the art to arrive at the present invention. EP '222 fails to teach a cover (17) above the reading area (15), does not disclose that cover (17) can be black, and does not disclose any advantage of using a black cover to absorb light because the light for measurement is not reflected in the invention of EP '222 due to the particular structure of the

analytical element. Therefore, one of ordinary skill in the art would not be motivated to modify the cover of JP '065 so that it is black based on the disclosure of EP '222.

It is respectfully submitted that the present invention is not *prima facie* obvious in view of JP '065 and EP '222.

With respect to claims 13-15, contrary to the Examiner's assertion at page 6 of the Examiner's Answer, Appellant has not made any admission that the structures covered by claims 13-15 would result if JP '065 and EP '222 were combined.

As discussed above, even if the references were somehow combined, the resulting structure would not have a black cover. The present invention according to claims 13-15 require a black cover because the claims depend from claim 11, which requires a black cover (i.e., dependent claims contain all the limitations of the independent claim from which they depend).

Therefore, the present invention according to claims 13-15 are not obvious in view of JP '065 and EP '222.

In addition, claims 13-15 are separately patentable for the following reasons. Claim 13 recites that the cover contacts one side of the reagent layer opposite to the support. Since neither JP '065 nor EP '222 disclose a cover in contact with a reagent layer, the present invention according to claim 13 is not taught or suggested. That is, EP '222 discloses a cover (17) in contact with an absorbent material (16); however, PE '222 does not disclose a cover in contact with a reagent matrix (14).

Claim 14 recites a light reflecting layer in contact with the reagent layer. EP '222 discloses a light reflecting or absorbing means comprising a flange positioned between the absorbent material and the read area, and preferably adjacent to the periphery of the read area. If EP '222 were applied to JP '065, it would not be possible to measure the reflected light. The detecting area (or measurement area) of JP '065 is located below the reagent layer. That is, the light analyzed is reflected back through small hole (11), which is located on side opposite of the reagent side. In other words, the measurement is not taken from the reagent side but from the side of the reagent layer fixed to the support (col. 4, lines 25-27). Thus, if a light reflecting or absorbing layer is formed to cover hole 11 because EP '222 teaches that the light reflecting or absorbing means is preferably adjacent to the read area, no measurements could be taken. Thus, the combination of JP '065 and EP '222 would render the device for analyzing liquid samples of JP '065 inoperative. Therefore, there is no motivation to combine the cited references because the resulting combination would not achieve the invention.

Claim 15 recites that the reagent layer comprises light reflective particles. EP '222 is silent with respect to whether the reagent matrix (14) comprises light reflective particles. Therefore, EP '222 does not teach or suggest the present invention according to claim 15.

In summary, it is respectfully submitted that JP '065 and EP '222 fail to teach or suggest the present invention.

CONCLUSION

For the above reasons as well as the reasons set forth in Appellant's Brief on Appeal, Appellant respectfully requests that the Board reverse the Examiner's rejections of all claims on Appeal. An early and favorable decision on the merits of this Appeal is respectfully requested.

Respectfully submitted,

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Date: July 26, 2004